



NDA 20-325/S-007

Merck Research Laboratories
Attention: George Latyszzonek
Sumneytown Pike, BLA-20
West Point, PA 19486

NOV 9 1998

Dear Mr. Latyszzonek:

Please refer to your supplemental new drug application dated December 20, 1996, received December 23, 1996 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Non-Prescription Pepcid AC and Mylanta AR Acid Reducer (famotidine) Tablets.

We acknowledge receipt of your correspondences dated February 27, April 24, May 14 August 18, and October 20, 23 and 28, 1998.

This supplemental new drug application provides for a revision to the "DIRECTIONS" section of the labels and labeling to change the time to take the drug prior to a meal to prevent meal-induced heartburn from "1 hour" to "15 minutes to 1 hour." This supplemental new drug application also provides for a revision to the graphical representation of the study results in the package insert concerning the prevention of heartburn symptoms for Pepcid AC and Mylanta AR Acid Reducer.

We have completed the review of this supplemental application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the draft labeling dated February 27, 1998 for Pepcid AC and in the draft labeling dated May 14, 1998 for Mylanta AR Acid Reducer, with the revisions listed below. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

As stated in your letters of October 20, 23 and 28, 1998, the revisions are as follows:

1. The following allergy warnings will be added:
 - A. For Mylanta AR Acid Reducer: **"Allergy warning:** Do not use if you are allergic to Mylanta AR Acid Reducer (famotidine) or other acid reducers."
 - B For Pepcid AC: **"Allergy warning:** Do not use if you are allergic to Pepcid AC (famotidine) or other acid reducers."

2. The storage temperature statement for both products will be changed from
“Store at a temperature up to 30°C (86°F)” to “Store between 250- 30°C (77°. 86°F).”

The following changes to the labeling of both products will be made in 180 days, or at the next printing, whichever comes first:

1. The statement of identity will be changed to “Famotidine Tablets 10 mg/Acid Reducer.”
2. The “DIRECTIONS” section on all labeling will be revised to replace all references to “swallow with water” with “swallow with a glass of water.” and only the words “**relieve**”, “**prevent**” and “**15 to 60 minutes before**” will be bolded to read, as follows:
 - To **relieve** symptoms, swallow 1 tablet with a glass of water.
 - To **prevent** symptoms, swallow 1 tablet with a glass of water at any time from **15 to 60 minutes before** eating food or drinking beverages that cause heartburn.
3. The location of the lot number and expiration date on all packaging will be identified.
4. In the upper top section of the front panel of the carton, dispenser, 7-panel bottle label, bottle card and pouches, the underline will be removed from the word “Prevents” in the phrase “Relieves and Prevents Heartburn and Acid Indigestion.”
5. To be consistent with other acid reducer drug products, under the “**Uses**” section in all the labeling, the bolding and underlining will be removed. To conform to the proposed new labeling format (Attachment), the “**Uses**” section will be revised to denote “heartburn” as the primary symptom, with other symptoms as secondary symptoms to read:
 - for relief of heartburn associated with acid indigestion and sour stomach
 - for prevention of heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages
6. In the “**Warnings**” section in all of the labeling, the “pregnancy-nursing warning” will be placed right before the “**Keep out of reach...**” warning statement.
7. On the back of the pouch labels, the tamper resistant/tamper evident statement will be removed from the “**Warnings**” section. The statement will be placed near the diagonal phrase “While folded on line, tear open at slit,” or right before the phrase “READ THE DIRECTIONS AND WARNINGS BEFORE USE.”
8. The tamper resistant/tamper evident statements “DO NOT USE IF THE INDIVIDUAL BLISTER UNIT IS OPEN OR BROKEN,” “DO NOT USE IF INDIVIDUAL BLISTER SEAL IS OPEN OR BROKEN,” and “DO NOT USE IF PRINTED FOIL INNER SEAL

UNDER BOTTLE CAP IS BROKEN,” will be revised by changing the word “BROKEN” to “TORN,” to now read “Do not use if. . . is open or torn.” For consumer readability both upper and lower case letters will be used. This change will be made for the tamper resistant/tamper evident statement found on the back panel of the 30-tablet carton, and the front page of the package insert (and in addition, for Pepcid AC, on panel #1 of the 7-panel bottle label, and the back panel of the bottle card). Additionally, on the back panel of the 50 tablet dispenser, the back panel of the child resistant sample pouch, and the back panel of the non-child resistant sample pouch, the statement “DO NOT USE IF POUCH IS OPENED” will include the words “or torn” to read: “ Do not use if pouch is open or torn.”

9. In the first bullet at the top of the back panel of the carton and the 50 tablet dispenser, the phrase “(Read Consumer Leaflet before use)” will be changed to read “(Read Package Insert before use).” You will also consider including the title “Package Insert” on the front panel of the package insert labeling to make it easier for the consumer to identify the package insert.
10. To be consistent with the other acid reducer products:
 - A. For Mylanta AR Acid Reducer; the word “treat” will be changed to “relieve” in the sentence: “Use Mylanta AR Acid Reducer to treat or prevent these symptoms” on the front page of the package insert and the left front panel of the 50 tablet dispenser under the section “How to Use Mylanta AR Acid Reducer.”
 - B. For Pepcid AC; the word “treat” will be changed to “relieve” in the sentence “Use Pepcid AC to treat or prevent these symptoms” on the front page of the package insert and the left front panel of the 50 tablet dispenser under the section “How to Use Pepcid AC.”
11. The text of bullet #3 under “Tips for Managing Heartburn” will be modified and simplified to read: “Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty, and fried foods, chocolate, caffeine, alcohol, and even some fruits and vegetables.”

As provided by your letter of October 23, 1998, the name “Pepcid AC Acid Controller” is changed in all labeling to “Pepcid AC .”

These revisions are the terms of approval for this supplemental new drug application. Marketing the products before making the revisions, exactly as requested, in the products’ final printed labeling (FPL) may render the products misbranded and unapproved new drugs.

Please submit 20 copies of the FPL for each product as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies, for each product, on heavy-weight paper or similar material. For administrative purposes, this submission should be designated “FPL for approved supplement NDA 20-325/S-007.” Approval of this submission by FDA is not required before the labeling is used.

If additional information relating to the safety or effectiveness of these drug products becomes available before we receive the final printed labeling, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Over-the-Counter Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about these drug products (i.e., a "Dear Healthcare Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of each drug product when it is available.

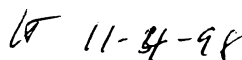
We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Al Rothschild, Project Manager, at (301) 827-2222.

Sincerely,



Debra Bowen, M.D.
Director,
Division of Over-the-Counter
Drug Products,
Office of Drug Evaluation V,
Center for Drug Evaluation and Research.



Lilia Talarico, M.D.
Director,
Division of Gastrointestinal and Coagulation
Drug Products,
Office of Drug Evaluation III,
Center for Drug Evaluation and Research.